

U.S.S.N. 10/511,121
International Application Filing Date: April 15, 2003
Section 371 (c) Date: March 28, 2005
AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Applicants thank the Examiner for indicating that claims 1-8, 11 and 16 have been allowed. Applicants also thank the Examiner for his helpful telephone interview on June 19, 2008.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 12-14, 17, 18, 21, 24 and 25 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

In his remarks, the Examiner indicates claim 12 recites a “device or machine” in the preamble but also recites two sliding surfaces sliding against each other. During the telephone interview, the Examiner suggested inserting the phrase “when in operation” after “other” in line 2 of the claim. Applicants have amended claim 12 as suggested by the Examiner. Therefore the scope of claim 12 is clear to one of ordinary skill in the art; and claim 12 and its dependent claims, claims 13, 14, 17, 18, 21, 24 and 25, are definite.

Rejection Under 35 U.S.C. § 101

Claims 12-14, 17, 18, 21, 24 and 25 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

During the telephone interview, the Examiner suggested inserting the phrase “when in operation” after “other” in line 2 of claim 12 to clarify that this claim defines a machine or device. Applicants have amended claim 12 as suggested by the Examiner. Therefore the scope

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of claim 12 and its dependent claims, claims 13, 14, 17, 18, and 21-25, define statutory subject matter.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 22-25 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The Legal Standard

The Court of Appeals for the Federal Circuit (CAFC) has described the legal standard for enablement under § 112, first paragraph, as whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art, without undue experimentation (*See, e.g., Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d at 165, 42 USPQ2d at 1004 (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *In re Fisher*, 427 F.2d at 839, 166 U.S.P.Q. at 24; *United States v. Electronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); *In re Stephens*, 529 F.2d 1343 (CCPA 1976)). Additionally, a patent need not teach, and preferably omits, what is well-known in the art (*see Falkner v. Inglis*, 448 F.3d 1357, 1365, 79 U.S.P.Q.2D 1001 (Fed. Cir. 2006), citing *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987)).

Whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See *In re Wands*, 858 F.2d 731, 735, 736-737, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). A determination of undue experimentation is a conclusion based on weighing many factors, not just a single factor. Many of these factors have been summarized in *In re*

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Forman, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) and are set forth in *In re Wands*. They are: (1) The quantity of experimentation necessary (time and expense); (2) The amount of direction or guidance presented; (3) The presence or absence of working examples of the invention; (4) The nature of the invention; (5) The state of the prior art; (6) The relative skill of those in the art; (7) The predictability or unpredictability of the art; and (8) The breadth of the claims.

There is no requirement for examples. *In re Borkowski*, 422 F.2d 904, 164 U.S.P.Q. (BNA) 642 (C.C.P.A. 1970). Further, patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Vaeck*, 20 U.S.P.Q.2D (BNA) 1438, 947 F.2d 488 (Fed. Cir. 1991).

Analysis

The Examiner alleged that the use of graft copolymers with polysaccharide chains was not enabled because the specification did not describe "how to make such graft copolymers." (Office Action at page 2, last para., last sentence). Although the Examiner correctly notes that the specification does not disclose how to make graft copolymers containing polysaccharide side chains, this is only one factor in the enablement analysis. As noted above, the enablement standard also requires analyzing what is known to one of ordinary skill in the art. Further, the enablement standard does not require an applicant to disclose how to make something if it is already known in the art. (*see Falkner v. Inglis*, 448 F.3d 1357, 1365, 79 U.S.P.Q.2D 1001 (Fed. Cir. 2006), citing *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534, 3 U.S.P.Q.2d

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1737 (Fed. Cir. 1987)). As shown below, methods for making the graft copolymers specified in claims 22-25 were known in the art at the time the priority application was filed.

Methods of making a graft copolymers containing a polyionic backbone that has a net positive or negative charge at neutral pH and side chains, where the side chains are neutral water-soluble polysaccharides, as specified in dependent claims 22 and 24, or dextran, as specified in dependent claims 23 and 25, were well-known to one of ordinary skill in the art prior to April 16, 2002, the priority date for the present application. The enclosed reference, Maruyama et al., "*Characterization of Interpolyelectrolyte Complexes between Double-stranded DNA and Polylysine Comb-type polymers having hydrophilic side chains*," *Bioconjugate Chem.*, 9:292-299 (1998), discloses forming a number of graft copolymers containing poly(L-lysine) (PLL) backbone and dextran graft side chains (*see e.g.* p. 293). Further Maruyama notes that "polysaccharides are suitable prepolymers for graft copolymer preparation, since most polysaccharides possess one reductive end." (p. 294, right col.)

Therefore, prior to the date of the priority application one of ordinary skill in the art knew how to make graft copolymers with polysaccharide sidechains, as specified in claims 22-25. Therefore the methods defined by claims 22 and 23 and the device or machine defined by claims 24 and 25 meet the enablement standard under 35 U.S.C. § 112, first paragraph.

Additional amendments to the claims

Claim 1 was amended to insert a missing comma.

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Applicants believe that all of the claims are in condition for allowance. However in the event that the Examiner has any objections to the claims, Applicants respectfully request an interview with the Examiner.

Claims 1-8, 11 and 16 have been allowed. Allowance of claims 12-14, 17, 18, and 21-25, as amended, is respectfully solicited.

Respectfully submitted,

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